

# Translating the Science on Neurotoxicants into Effective Policy

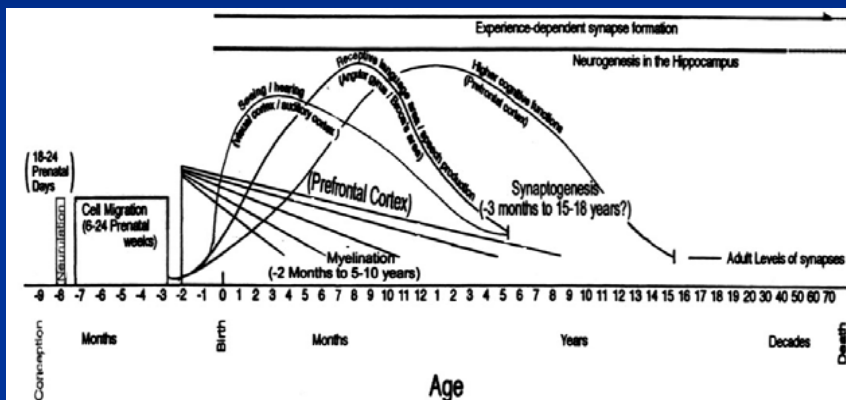
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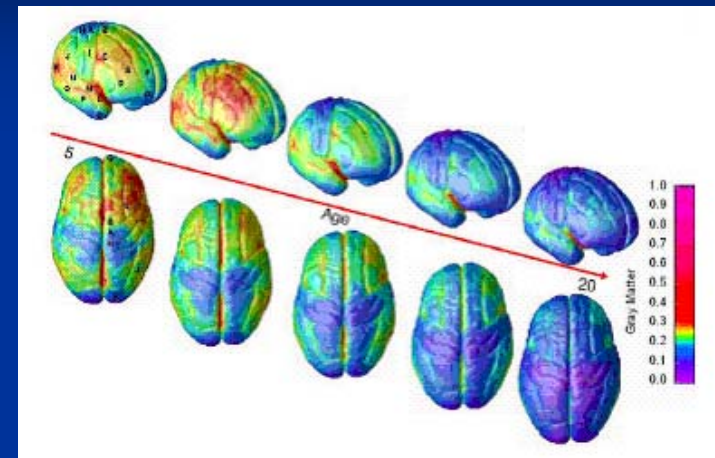
## Developmental disabilities

- Among the most important child health problems in the US
  - 17% of children have a developmental disability
  - 2% have a “severe” disability requiring special education (CDC)
  - 3-7% of children have attention deficit hyperactivity disorder (ADHD) (APA)
  - 6 in 1,000 children have some form of autism spectrum disorder (CDC)
  - Unfortunately, we know very little about the causes of such disorders

## Course of human brain development (Thompson and Nelson 2001)

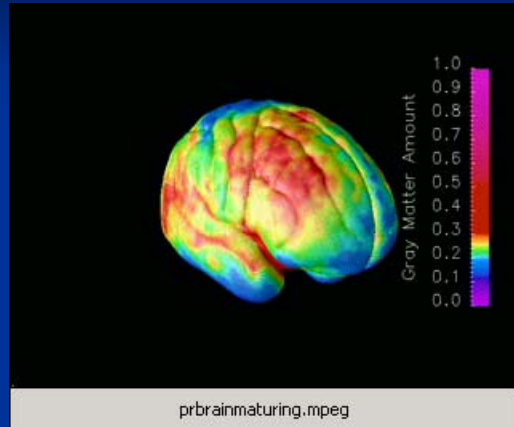


## Time-Lapse Imaging Tracks Brain Maturation from ages 5 to 20



Source: Paul Thompson, Ph.D.  
UCLA Laboratory of Neuroimaging

## Brain maturation: Ages 5-20



Source: Paul Thompson, Ph.D.  
UCLA Laboratory of Neuroimaging

## Prevention is Key

- Lower levels of a vitamin, folate, have been linked to neural tube defects
- Rates of this birth defect have sharply declined since the introduction of folic acid supplements into the US diet.



This baby was born healthy.



This vitamin may have helped.

## Role of Chemicals

- A number of persistent pollutants – lead, polychlorinated biphenyls and dioxins, and methyl mercury – have been linked with developmental neurotoxicity in children.
- However, we do not know the role of these, and other environmental exposures, in developmental disabilities.

## Environmental Policy Efforts

- Testing of chemicals and pesticides for developmental neurotoxicity effects;
- Expanding funding for tracking developmental disabilities and researching their etiologies; and
- Controlling persistent pollutants, many of which are developmental neurotoxicants

## Pesticide Developmental Neurotoxicity Testing

- 1993 Report Pesticides in the Diets of Infants and Children
- Progress since 1993
  - 1995 EPA's DNT guideline
  - 1996, Food Quality Protection Act, for pesticides
  - 1999, EPA issued a data call-in for organophosphate pesticides
  - No other data call-ins have been issued and no final results for OPs

## Testing Other Chemicals at EPA

- EPA, chemical industry, and Environmental Defense "High Production Volume (HPV)" chemical testing program
- EPA and American Chemistry Council Voluntary Children's Chemical Evaluation Program (VCCEP)
- Endocrine Disruptor Screening and Testing Program (EDSTP)

## FDA Assessment of Developmental Neurotoxicity

- Currently assessing pediatric effectiveness and hazards associated with certain drugs that are already on the market. [Best Pharmaceuticals for Children Act (PL-No. 107-109), 2002]
- FDA has not yet adopted a protocol for developmental neurotoxicity testing of drugs or other agents it regulates [e.g., food additives, cosmetics]



## Developmental Neurotoxicity Test

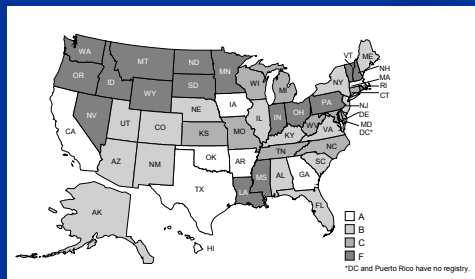
- Controversies:
  - Is it adequate for detection of disruption of all components of neurodevelopment, and over the full developmental time span?
  - Does it use too many animals?
  - Should it be “triggered” by other tests?
- The OECD harmonization process
  - Begun in 1996
  - September 2003 final draft guideline

## Developmental Neurotoxicity Testing Recommendations

- Research to develop better predictive models
- Research to better understand mechanisms for neurotoxicity
- Commitment to generate information (by government and industry alike) needs to be there

## Tracking and Research Efforts

- 1999 Pew Environmental Health Commission report *Healthy From the Start: Why America Needs a Better System to Track and Understand Birth Defects and the Environment*.
- Recommended establishment of a nationwide health tracking system



## Progress since 1999

- The US Centers for Disease Control and Prevention (CDC) Centers of Excellence for tracking rates of autism and other developmental disabilities
- California autism research
- Private funding (e.g., March of Dimes, CAN)
- CDC state environmental public health surveillance projects and Centers of Excellence
- NIEHS/EPA Children's Environmental Health Research Centers.



## Tracking and Research Recommendations-1

- Continue to expand and support the National Environmental Health Tracking System, specifically:

- Birth defects and developmental disabilities
- Neonatal outcomes
- Neurological outcomes
- Environmental exposures



## Tracking and Research Recommendations-2

- What we do know has largely been derived from epidemiology studies of neurological outcomes among children exposed in utero and in early life
- We need a large longitudinal study to examine the associations between early childhood exposures and subsequent neurodevelopmental outcomes and disabilities – hopefully – the National Children's Study

## Control of Persistent Pollutants

- Global POPs Convention (Stockholm Convention on Persistent Organic Pollutants)
  - Covers the “dirty dozen” POPs chemicals and pesticides
  - Such pollutants move around the globe; once they have entered the environment; you can't just turn off the tap.
  - Chemicals included are: the pesticides aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, and hexachlorobenzene; the industrial chemicals PCB's; and the inadvertent contaminants dioxins and furans.

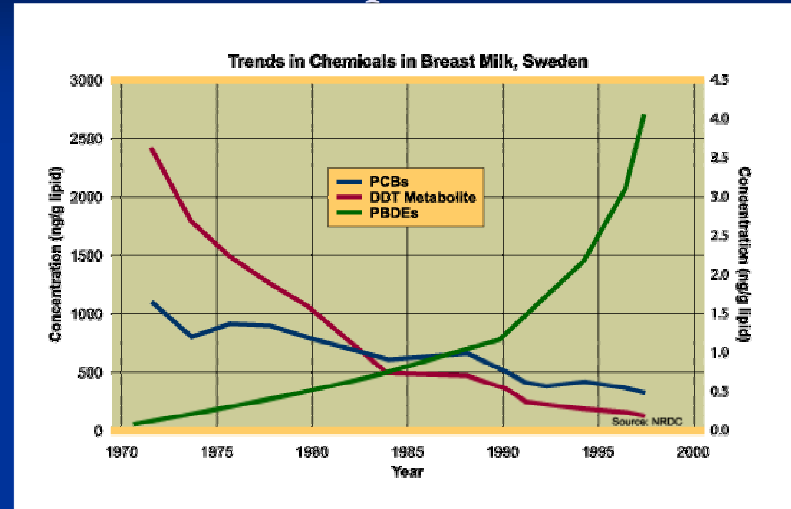
## Actions under the POPs Convention

- Most of the “dirty dozen” are scheduled for a complete phase-out
- DDT has a public health exemption to allow for its use in malaria control.
- Dioxins and furans are not phased out but rather “phased down”
- The US government has signed, but the Bush Administration has not ratified, this agreement.
- Without the US the Convention comes into force this month

## Problems: New and Old

- Flame retardants
- Perfluorinated chemicals
- Lead
- Mercury

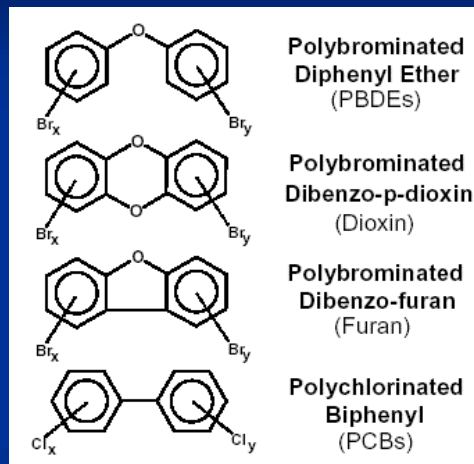
## PBDE Time Trend in Human Exposure



(Natural Resources Defense Council 2001)

## Flame Retardants

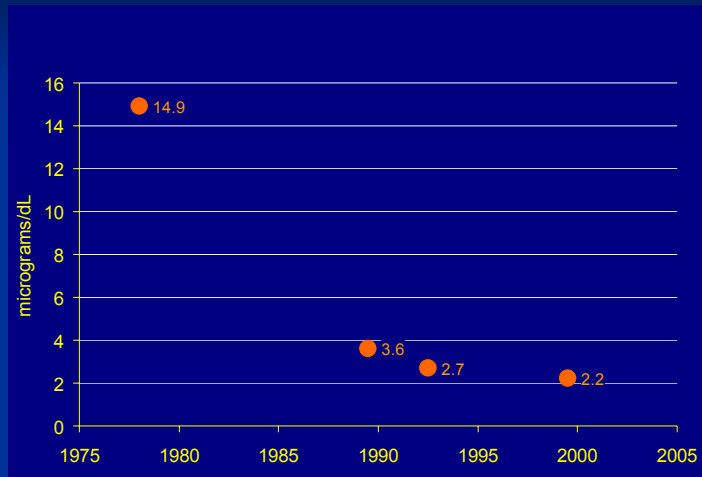
- Levels of polybrominated diphenyl ethers or PBDEs (flame retardants) have increased in the breast milk of Swedish women.
- Europe has banned or restricted these chemicals.
- States have begun to take action, beginning with legislation enacted last year in California.



## Perfluorinated Compounds (PFCs)

- In May, 2000 perfluorooctanyl sulfonate, a chemical used in 3M's Scotchguard (r), was found to persist in the environment, and to accumulate in human and animal tissues.
- 3M identified toxic effects to developing animals, at high doses
- EPA and 3M voluntary phase out
- October 2000, the EPA proposed "significant new use rule".
  - Rule is not final
  - Rule will not decrease existing uses

## Lead: A Public Health Success



## Lead: Remaining Risks

- One of the oldest and most familiar of persistent and toxic substances.
- Regulation of lead in gasoline, water and food sources, paint and consumer products has resulted in dramatic decrease in lead levels in the US over time but leaded gasoline and other risks still prevalent worldwide
- 2002: UN Environmental Program governments agreed to phase out leaded gasoline globally.

## Lead: US

- The US still has pockets of lead exposure, mostly due to lead contaminated housing
- At last count, the CDC estimated that some 300,000 children under six have blood lead levels greater than 10 micrograms/deciliter
- New sources of concern, for example, the recent news of high lead levels in drinking water in the District of Columbia
- Evidence (Lanphear, Bellinger) supports a lower target for lead toxicity, of 5 micrograms/deciliter



## Mercury: Progress in the 1990s

- Mercury is another important persistent substance
- Methylmercury is a potent developmental neurotoxicant.
- Reductions in emissions in 1990s:
  - EPA regulations on municipal and medical waste incinerators (which used to be the most important sources)
  - Voluntary reductions in emissions from some chloralkali production plants
  - Waste clean-ups

## Mercury: Progress Stalled in 2000s

- “New Source Review” ended by Bush Administration
- EPA’s “Clear Skies” legislative proposal to amend the Clean Air Act
- EPA’s proposed rule for mercury from utilities
- Yet utilities are now the most significant uncontrolled source of mercury to the US environment



## EPA’s Mercury Regulatory Proposal

- December 2003
- Set goals (and timetables) for mercury reduction that are much less than what could be achieved with best available technology (according to EPA’s staff analysis)
- Allows for mercury trading, which could create mercury “hot spots”
- EPA has delayed the final regulation (until December 2005)



## Mercury Risks

- EPA’s scientists have concluded that there are 340,000 - 620,000 babies born every year in the US with methylmercury exposures above EPA’s reference dose
- Most exposure is via consumption of contaminated fish
- The FDA has not yet adopted a more stringent standard recommended by the National Research Council



## Control of Persistent Pollutants- Recommendations

- The US needs to ratify and support the Global POPs convention and also global efforts to control lead in gasoline
- The situation with lead, flame retardants and PFCs argues for a fundamental overhaul of how EPA regulates chemicals, especially persistent chemicals
- It is important to insist on strict adherence to the laws that are in place, like the Clean Air Act, and resist Bush Administration efforts to weaken them
- FDA needs to strengthen its approach to mercury protection





# Conclusions



- We have come a long way
- BUT
- We have a long way to go